Attorney Docket No. F-5733 PATENT
W&W Ref: 1417P P 596



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|---|---|
| **In re U.S. Patent Application of:** | ) |
| **Kok-Hwee Ng et al.** | ) |
| | ) |
| **Serial No: 09/864,891** | ) **Examiner: Unknown** |
| | ) |
| **Filed: May 24, 2001** | ) **Art Unit:** |
| | ) |
| **For:** A SYSTEM AND METHOD FOR COMPILING AND VIEWING INFORMATION OF DATA ACTIONS WITHIN A BLOOD COLLECTION FACILITY | ) |



**PRELIMINARY AMENDMENT**

BOX NON-FEE AMENDMENT
Commissioner for Patents
Washington, DC 20231

Sir:

Prior to examination of the above-identified application, please amend the application as follows:

**In the Specification:**

Please delete the noted paragraphs and replace them with paragraphs printed below (marked up copies of the corresponding pages are attached as Attachments A, B, and C).

Please delete the paragraph beginning on page 6 at line 9 and ending on page 6 at line 25 with the following paragraph:

- - The present invention is directed to an apparatus or system for collecting, using, and

storing information in a biological fluid collection and/or processing facility ("facility"). The present invention can be incorporated into an existing facility's system via an upgrade to existing hardware and software. The present apparatus provides a data connection between laboratory instruments, including, but not limited to, existing blood and blood component collection instruments, such as the Autopheresis-C instrument which is supplied by the Fenwal Division of Baxter Healthcare Corporation located in Deerfield, Illinois, those described in PCT Publication No. WO 01/17584, U.S. Patent Nos. 5,581,687 and 5,956,023, and U.S. Serial No. 09/037,356, and biological treatment instruments, such as the pathogen inactivation instruments described in U.S. Serial No. 09/325,599, which are all assigned to Baxter and are incorporated by reference herein, and the collection facility's management information system which lends itself to automated tracing and/or tracking of donors and biological fluids data logging. Traceability is provided via integration of donor, operator, soft goods, and instrument data. The present invention further automates event reporting which is required for regulatory compliance. - -

Please delete the paragraph beginning on page 8 at line 16 and ending on page 8 at line 24 with the following paragraph:

- - In a second embodiment illustrated in Figure 2, the apparatus 10 comprises hardware and software component parts and provides for inter-process communication. Figure 2 shows a first network 12. The first network 12 includes laboratory instruments 20a, 20b, 20c, serial/parallel to Ethernet converters 24a, 24b, 24c , such as a PicoWeb™ device by Lightner Engineering located in San Diego, California or a NetDev™ device by Fenwal Division of Baxter Healthcare Corporation,

where needed, a first Ethernet 30, and a system server 34 including a memory, a communication driver for the apheresis instruments, a communication protocol converter, and an HTML application with embedded javascript code. - -

Please delete the paragraph beginning on page 62 at line 29 and ending on page 63 at line 5 with the following paragraph:

- - The system 10 also allows a facility to gather data from the laboratory instruments. This data can be monitored in real time, or near real time, from remote locations, the workstation(s), or the PDAs. The present system has the ability to convert parallel data to Ethernet which allows the data to be seen using a common web browser. This enables present system to be integrated into existing blood collection facilities that utilize legacy apheresis instruments having a proprietary pin arrangement, such as the Autopheresis-C plasmapheresis instrument supplied by the Fenwal Division of Baxter Healthcare Corporation. The data conversion is accomplished by the serial/parallel to Ethernet converters or NetDev™ devices 24a, 24b, 24c. - -

## REMARKS

Applicants respectfully request that this Amendment be entered.

The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 23-0280. A duplicate copy of this sheet is attached.

_X_ Any patent application processing fees under 37 C.F.R. 1.17.

Date: August 24, 2001

Respectfully submitted,

By: _____

Peter M. Klobuchar 43,722
WALLENSTEIN & WAGNER, LTD.
311 South Wacker Drive, 53rd Floor
Chicago, Illinois 60606
312.554.3300
Attorney for Applicants

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is, on the date shown below, being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: BOX NON-FEE AMENDMENT, Commissioner of Patents, Washington, D.C. 20231 on August 24, 2001.

_____
Gerianne M. Flannery (128853.1)

## ATTACHMENT A

The present invention is directed to an apparatus or system for collecting, using, and storing information in a biological fluid collection and/or processing facility ("facility"). The present invention can be incorporated into an existing facility's system via an upgrade to existing hardware and software. The present apparatus provides a data connection between laboratory instruments, including, but not limited to, existing blood and blood component collection instruments, such as the Autopheresis-C instrument which is supplied by the Fenwal Division of Baxter Healthcare Corporation [International, Inc.] located in Deerfield, Illinois, those described in PCT Publication No. WO 01/17584, U.S. Patent Nos. 5,581,687 and 5,956,023, and U.S. Serial No. 09/037,356, and biological treatment instruments, such as the pathogen inactivation instruments described in U.S. Serial No. 09/325,599, which are all assigned to Baxter [International, Inc.] and are incorporated by reference herein, and the collection facility's management information system which lends itself to automated tracing and/or tracking of donors and biological fluids data logging. Traceability is provided via integration of donor, operator, soft goods, and instrument data. The present invention further automates event reporting which is required for regulatory compliance.

## ATTACHMENT B

In a second embodiment illustrated in Figure 2, the apparatus 10 comprises hardware and software component parts and provides for inter-process communication. Figure 2 shows a first network 12. The first network 12 includes laboratory instruments 20a, 20b, 20c, serial/parallel to Ethernet converters 24a, 24b, 24c , such as a PicoWeb™ device by Lightner Engineering located in San Diego, California or a NetDev™ device by Fenwal Division of Baxter Healthcare Corporation [International, Inc.], where needed, a first Ethernet 30, and a system server 34 including a memory, a communication driver for the apheresis instruments, a communication protocol converter, and an HTML application with embedded javascript code.

## ATTACHMENT C

The system 10 also allows a facility to gather data from the laboratory instruments. This data can be monitored in real time, or near real time, from remote locations, the workstation(s), or the PDAs. The present system has the ability to convert parallel data to Ethernet which allows the data to be seen using a common web browser. This enables present system to be integrated into existing blood collection facilities that utilize legacy apheresis instruments having a proprietary pin arrangement, such as the Autopheresis-C plasmapheresis instrument supplied by the Fenwal Division of Baxter Healthcare Corporation [International, Inc]. The data conversion is accomplished by the serial/parallel to Ethernet converters or NetDev™ devices 24a, 24b, 24c.